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Functional visual tests to evaluate the effect of small astigmatism correction with toric contact lenses

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Abstract: The prescription of daily contact lenses does not often include a full astigmatic correction. We question here whether this full astigmatic correction (for low to moderate astigmatism) provides a substantial improvement in the overall visual performance compared to a more conservative approach based only on the prescription of spherical contact lenses. The visual performance of 56 contact lens neophytes divided in two contact lens fitting groups (toric versus spherical lens fit) was assessed using standard visual acuity and contrast sensitivity tests. A new set of functional tests simulating everyday tasks was also used. Results showed that subjects with toric lenses had significantly better visual acuity and contrast sensitivity than those with spherical lenses. Functional tests did not render significant differences between groups, which was explained by several factors like i) the visual demand of the functional tests, ii) the dynamic blur due to misalignments and iii) small misfits between the available and measured axis of the astigmatic contact lens.

1. Introduction

Astigmatism is a common refractive error. It is estimated that about 60% of the adult population has at least 0.25 D of ocular astigmatism and that at least 20% of the population has astigmatic refractive errors greater than 0.50 D [1–3]. Its high prevalence and its impact on visual performance make the adequate management of its correction a very important issue.

There is a variety of refractive corrections currently available to treat astigmatism, including spectacles, contact lenses (CLs), refractive surgery or intraocular lenses. These technologies usually provide complete astigmatism correction. However, there is one case where this is not always true: the prescription of daily-disposable contact lenses. Although toric CLs can correct astigmatism in most cases, it is an expensive solution in a daily-disposable basis. Alternatively, spherical CLs with power corresponding to the spherical equivalent of the manifest refraction are a less expensive option when managing low to moderate astigmatism and they avoid technical difficulties specific to toric CLs, such as ensuring rotational stability. The cost to pay is a presumably lower Visual Acuity (VA). It is estimated that only 25% of CLs prescribed worldwide have toric correction, this percentage decreasing to 14% if we restrict exclusively to daily CLs [4].

Despite induced astigmatism less than or equal to 0.75 D has been proven to affect VA [5,6], from a clinical point of view, correction of astigmatism below 0.50 D is not worth value [7]. Regarding cylinder orientation, there is controversy in the literature about its impact on VA. There are several studies which conclude that axis orientation has no influence on VA [8,9], whereas other studies show the opposite effect [10,11]. Moreover, it has been shown that the eye is a robust optical system in which the cornea and lens are arranged in such a way that they

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compensate for each other to produce images with higher optical quality and less aberrations [12–15]. Thus, it might be questioned whether these fully corrective lenses provide a substantial cost-effective improvement in overall visual performance, particularly single-use CLs with low and moderate astigmatism starting at 0.50 D of cylinder.

Conventional clinical tests in which VA and Contrast Sensitivity (CS) are assessed provide valuable information about the visual quality of patients. However, such tests do not provide information about how a particular type of visual correction impacts patients' quality of life from a practical point of view when performing daily tasks. It is convenient to develop functional tests in which patients' performance in everyday activities is quantitatively assessed [16,17]. The purpose of this type of tests is not to replace standard tests, but to provide additional information and to obtain a more complete evaluation of the overall visual performance of patients under different circumstances.

For this reason, a study comparing these two approaches of astigmatism correction was carried out, including the measurement of both conventional (VA and CS) and functional visual tests, in which a set of daily activities with an important visual demand were assessed. Functional tests will include (i) reading a text, (ii) writing an e-mail and searching documents in a computer, (iii) pouring liquid into a recipient up to a certain predefined level, and (iv) opening a lock and screwing in a bolt.

2. Methods

2.1. Participants

The study was approved by the Ethics Committee of the University of Murcia (Spain). It followed the tenets of the Declaration of Helsinki, and all subjects gave informed written consent prior to any measurement. All participants in the study were CL neophytes. The motivation for this is to avoid the possible effect that has been shown according to which the brain can compensate for familiar aberrations in such a way that the visual sensation is clearer and sharper than it should be if only optical aspects were considered [18]. In the first visit to the laboratory, examiners checked both eyes to see if exclusion and inclusion criteria were matched, including VA assessment and clinical slit lamp analysis of the anterior pole and ocular surface. Due to limited CL power range and the high demanding visual tasks included in the study, the following inclusion criteria were included:

(i) Refractive astigmatism (spectacles) ranging from -0.50 to -2.00 D.

(ii) Myopia less than or equal to -6.00 D.

(iii) VA corrected with glasses greater than or equal to 0.05 LogMAR.

In addition, hyperopic subjects as well as all participants with any ocular condition that can affect the ocular surface, as active pathology or ocular surgery, or reduced contact lens comfort were also excluded.

Afterward, subjects were randomly selected for each CL group (spherical or toric). To avoid possible biases, subjects were not informed about the type of CL correction that they were selected for (single-blind study). Both groups were homogeneous, matched by age and refractive error with no statistically significant differences within these variables ($p > 0.05$). Subjects in group one (SEQ; $N = 28$; age 22 ± 3 years; sphere -2.3 ± 0.9 D; cylinder -1.0 ± 0.3 D) were monocularly fitted with a soft spherical contact CL (PRECISION1 Alcon Laboratories, Inc, Fort Worth, TX; 49% verofilcon A, 51% water; $ø = 14.2$ mm; Base Curve = 8.3 mm). Subjects in group two (TOR; $N = 28$; age 22 ± 4 years; sphere -2.3 ± 1.3 D; cylinder -1.0 ± 0.3 D) were monocularly fitted with a soft toric CL (PRECISION1 for Astigmatism; 49% verofilcon A, 51% water; $ø = 14.5$ mm; Base Curve = 8.5 mm; Stabilization System: PRECISION BALANCE 8|4).

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2.2. Vision assessment

A mixed objective/subjective refraction was provided by a Visual Adaptative Optics Simulator (VAO; Voptica SL, Murcia, Spain). Validation and repeatability data of this device and this procedure are available elsewhere [19,20]. Briefly, VAO automatically performs objective aberrometry based on three Hartmann-Shack wavefront sensor images. Based on these data, the device calculates an objective refraction that is selected as the starting point for a subjective refinement of refraction, also performed within the same device. The subjective (monocular) refraction assesses the Maximum Plus that gives the Maximum Visual Acuity (MPMVA). Cylinder was refined using cross-cylinders. Fogging technique was used to control accommodation during the subjective exam. Monocular far Best Corrected Visual Acuity (BCVA) was measured with VAO as well. All tests were performed monocularly. If both eyes met the inclusion criteria, then the dominant eye was selected by means of the Miles test [21].

In a second visit, each participant was fitted with the CL corresponding to their group. Since the toric lenses cylinder axis was available in 10-degree steps, the closest available value to the measured axis was chosen. After waiting for half an hour, the ocular surface as well as the lens behavior and correct position of the cylinder axes were assessed by means of the slit lamp examination. In addition, a subjective over-refraction was performed again using VAO in order to evaluate possible residual refractive errors. In both groups, when the residual sphere was higher than 0.50 D (in absolute value), the contact lens was replaced. Additionally, in the TOR group the lens was also replaced if the axis angle was incorrect. An ETDRS test with letters was used to measure VA (Fig. *1*). When subjects could not see all the letters on one line of the chart, each letter was assigned a VA value (depending on the reading line) such that the acuity measured is equal to the acuity of the last completed level plus the acuity corresponding to the number of letters read over the incomplete level. This measure was also repeated for close reading at simulated distances of 40 cm and 60 cm. Far CS thresholds were measured at frequencies of 9 and 15 c/deg by a forced-choice method where subjects must identify the orientation of fringes between three possible options (vertical, right oriented or left oriented). In this test, the threshold was determined as the lowest contrast level in percentage at which the subject can distinguish the orientation of the fringes with the given spatial frequency (Fig. *1*).

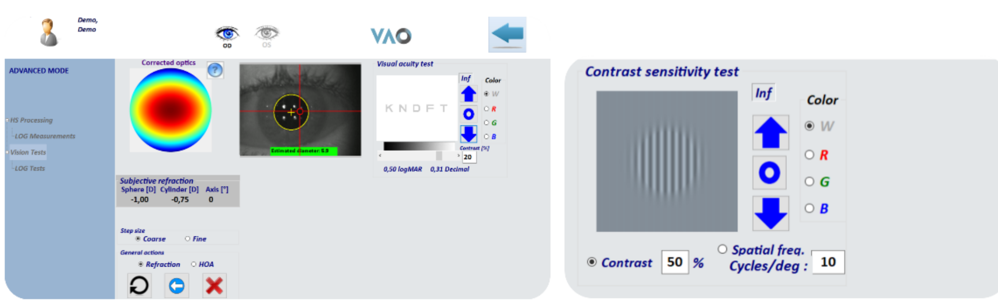

Fig. 1. VAO display for measuring Visual Acuity (left) and Contrast Sensitivity (right) tests.

2.3. Functional tests

After performing the conventional visual tests, the participants carried out four functional tests designed as a diverse group of activities that adequately represent daily tasks of different nature for which good vision may be necessary [16,22–25].

E-mail test. Subjects had to write an e-mail to a given address with three attachments selected from a fully populated desktop screen consisting of 112 documents with names of animals in alphabetical order distributed in a matrix of 7 rows and 16 columns. Subjects had to attach the

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files one at a time. A 23.6” screen located 60 cm from the subject was used. The time taken to complete the task was self-automatic measured with a virtual stopwatch located in the upper right corner of the screen.

Reading test. Subjects read two paragraphs of 92 and 97 words divided into six lines (Arial 10 font) shown on a 23.6” screen with a resolution of 1920 × 1080 pixels at a reading distance of 60 cm. Characters were discretized into ~8 pixels on average with a fine detail length of 1 pixel (0.27 mm), corresponding to a visual acuity of 0.20 LogMAR. Reading performance parameters (reading time, number and duration of fixations, number and ratio of regressions and magnitude of saccades) were recorded using an eye tracking device (GP3 HD, Gazepoint, Vancouver, Canada) at a frequency of 150 Hz. Validation data of this device are available [26].

Level test. (Fig. 2) Subjects had to take a graduated test tube containing 50 mL of blue-colored water and pour the liquid into another graduated test tube to a predefined level of 35 mL. Subjects were seated and were allowed to change their viewing distance. The test was performed three times per subject. The time to complete the task was measured with an Arduino stopwatch based on a pressure sensor, so that it starts counting the time when the subject picks up the first test tube and stops when he puts it back on the sensor. In addition, a video of the test was recorded by a color video camera (DFK 33UX174, The Imaging Source, Bremen, Germany) at 30 fps. From the videos we obtain the height error made by the subject, defined as the difference between the level reached by the liquid and the target level, and a real-time filling profile.

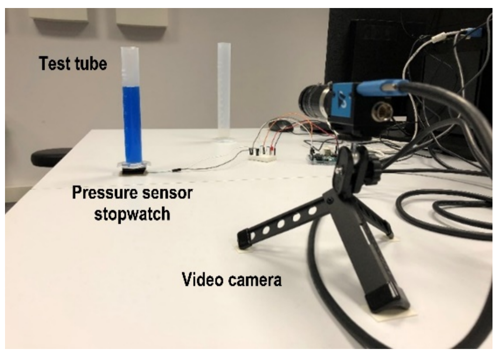

Fig. 2. Level test.

Lock test. (Fig. 3) Subjects had to take a key to open a lock box, take the bolt placed inside the box and screw a nut to a mark drawn on the bolt. The test was performed three times per subject and the time to complete the task was measured with an Arduino stopwatch based on a pressure sensor. Similar to the level test, the stopwatch starts timing when the subject picks up the key, initially placed on the sensor, and stops counting when he leaves the bolt on it.

2.4. Data analysis

The means of the two groups were compared using unpaired t-tests. Significance level was set at $p < 0.05$. If the normality test (Shapiro-Wilk test) failed, non-parametric tests (Mann-Whitney U test) were used instead.

For quantities measured over several repetitions, the mean value was used. Wolfram Mathematica (Wolfram Research, Champaign, IL, USA) was used for the statistical analysis of the data and to extract reading performance parameters from the raw data provided by the eye tracking device. In the level test, customized routines were programmed in MATLAB (The MathWorks, Natick, MA, USA) to process the videos and automatically measure the final test level.

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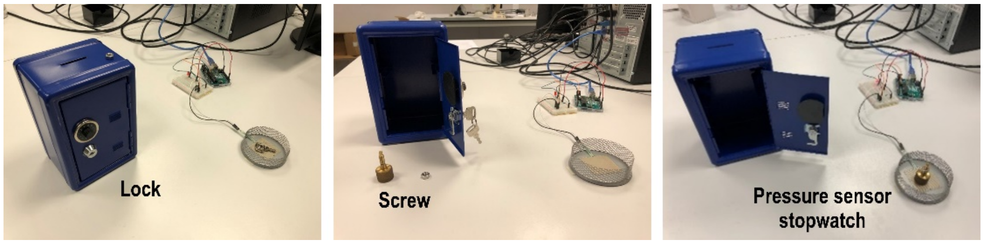

Fig. 3. Lock test. (a) Subjects start the test with the lock closed and the key placed over the pressure sensor. (b) After opening the lock, subjects take a bolt out of the box and screw in a nut to a predefined level. (c) When they finish the task, they place the screw over the pressure sensor to stop the time.

3. Results

No safety events as adverse events or device deficiencies were reported during the whole duration of the study. A total of 56 participants were involved in the experiment, divided into 28 subjects for each group. The SEQ group included 12 males and 16 females, with an age range between 18 and 30 years (average of 22 ± 3 years) and with a mean power of the fitted CL of Sph = -2.7 ± 0.9 D. The TOR group included 10 males and 18 females, with an age range between 18 and 27

Table 1. Results for the functional and visual tests.[a]

	SEQ	TOR	p-value
Visual Acuity test			
VA far, LogMAR	0.02 (0.06) #	-0.05 (0.06) #	< 0.001
VA at 60 cm, LogMAR	0.06 (0.08) #	-0.03 (0.07) #	< 0.001
VA at 40 cm, LogMAR	0.09 (0.13) #	-0.01 (0.07)	< 0.001
Contrast Sensitivity test			
9 c/deg	18.6 (6.5)	24.8 (10.1) #	0.02
15 c/deg	8.7 (3.5)	10.5 (4.7) #	0.16
E-mail test			
Total time, s	45.1 (7.9) #	42.9 (10.2)	0.20
Reading test			
Reading time, s	33.5 (5.0) #	33.7 (4.7) #	0.45
Number of fixations	99.3 (25.1)	98.8 (26.7)	0.91
Duration of fixations, s	0.33 (0.08) #	0.34 (0.08) #	0.70
Number of regressions	19.8 (11.8) #	18.4 (10.7) #	0.49
Saccade magnitude, px	58.4 (8.3) #	59.5 (9.3) #	0.49
Rate of regressions	20.7 (7.8)	19.0 (6.5)	0.21
Level test			
Filling time, s	18.1 (6.3)	17.4 (6.1) #	0.65
Filling error, mm	1.65 (1.08) #	1.73 (0.89) #	0.44
Lock test			
Total time, s	12.9 (2.4)	13.1 (2.5)	0.74

[a]Values for SEQ and TOR columns are Mean (SD).
[a]Data with # are not normally distributed.

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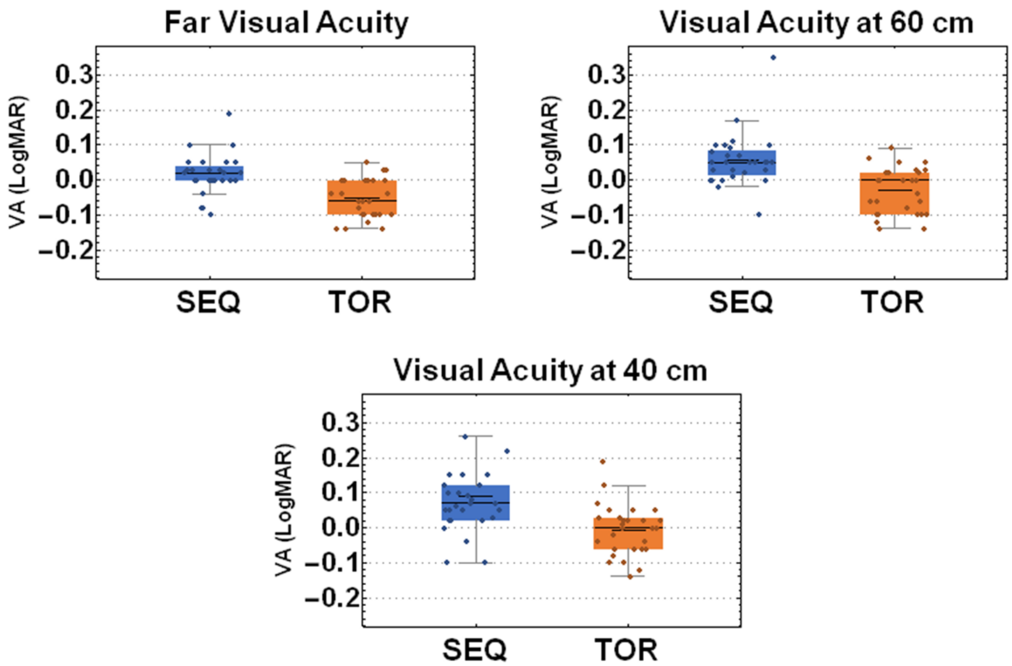

Fig. 4. Results for visual acuity for far, 60 cm and 40 cm distances. Quartiles are represented in the box-and-whisker plots. The median and mean of the data are represented by the long and short lines, respectively. Data are represented by dots.

years (average of 22 ± 4 years) and with a mean power of the fitted CL of Sph = -2.3 ± 1.3 D, Cyl = -1.0 ± 0.4 D. All subjects in the SEQ group had compound myopic astigmatism. In the TOR group, 26 subjects had compound myopic astigmatism and 2 had simple myopic astigmatism. The residual astigmatism (obtained from the VAO from the measurement of LOA) was Cyl = -0.89 ± 0.47 D for the SEQ group and Cyl = -0.44 ± 0.32 D for the TOR group. On Table 1 a summary of the mean values and the standard deviations is shown for all the main variables considered in this study. Difference between SEQ and TOR groups was also tested.

VA was clearly better for the TOR group than for the SEQ group at all measured distances ($p < 0.001$). On average, the difference between both groups was around two lines in the acuity chart: 0.07 LogMAR for far, 0.09 LogMAR for 60 cm reading distance and 0.10 LogMAR for 40 cm reading distance (Fig. 4). The same trend was also observed in the CS tests, with subjects from the TOR group performing better than those from the SEQ group (Table 1) for the two spatial frequencies considered in the experiment (Fig. 5). However, the difference between groups was statistically significant only in the case of 9 c/deg ($p = 0.02$).

For the e-mail test, the execution time was on average slightly shorter (2.2 seconds) for the TOR group than for the SEQ group. However, this difference between the groups is not statistically significant.

In general, the reading performance was similar between groups and there were no significant differences in any of the parameters. It was interesting to observe that, on average, the rate of saccade regressions was lower for the TOR group, which may indicate a slightly more fluent reading by subjects with the toric lens. However, as mentioned above, the differences between the groups were small and not statistically significant.

A similar situation was found for the level test. Regarding the filling error, defined as the difference (in absolute value) between the target level and the achieved level, the performance

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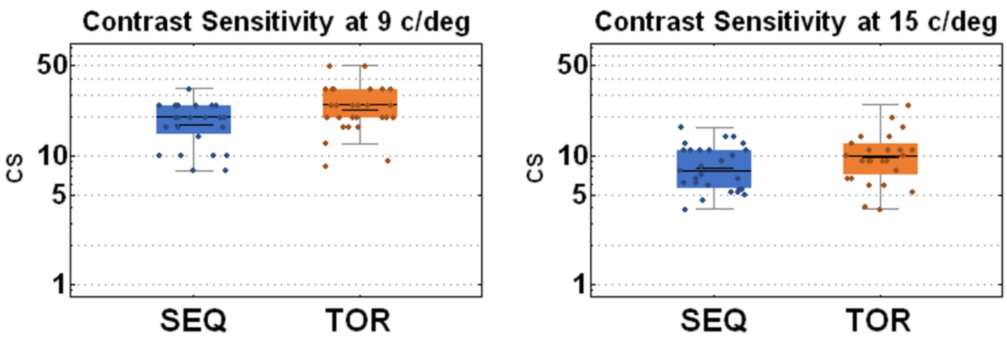

Fig. 5. Contrast sensitivity for 9 and 15 c/deg. Quartiles are represented in the box-and-whisker plots. The median and mean of the data are represented by the long and short lines, respectively. Data are represented by dots.

was very similar in both groups and no significant differences were found between them. On the other hand, the execution time of the task tended to be lower for the TOR group (median 15.1 s) than for the SEQ group (median 17.5 s). However, the observed trend was not statistically significant.

As for the lock test, as in the previous functional tests, no significant differences were found in the total execution time between the SEQ and TOR groups.

4. Discussion

In general, imperfect optical corrections present no visual benefits for the eye. We demonstrated here that the full correction of astigmatism (sphere and axis) with disposable toric contact lenses significantly improved visual quality (VA and CS at 9 c/deg) compared to a partial correction with only spherical contact lenses. Therefore, there is no possible optical or visual reason for a lack of a full astigmatic prescription. This result applied to a population with low to moderate cylinders (from 0.50 D to 2.00 D). This is not the case for astigmatism values below 0.50 D, where full correction offers no benefit from a clinical point of view [7].

We also designed a set of functional tests to check the impact of the astigmatic corrections on daily activities. There were no statistically significant differences on the functional vision parameters between groups fitted with the different contact lenses, in part due to the high inter-individual variability (even with a specially selected homogenous population). The reason for this variability is discussed in the following paragraphs. Still, looking at the overall data, some tasks were completed faster by subjects fitted with a toric lens than by those fitted with the spherical lens. These particular tasks might be interesting for further investigations. Perhaps, if those tasks were performed under less favorable conditions (i.e., poorer illumination) and with more visually demanding tasks (smaller letters and/or a higher level of discrimination) they could be useful to find fine differences between both groups.

These results also suggest that the visual system and hand-eye coordination exhibit a certain level of robustness against low refractive errors equivalent to having about two lines in the acuity chart. And that, perhaps, in a variety of daily activities, different aspects of vision were only *selectively* involved, including either the ability to distinguish fringes (CS) or to discriminate static letters (VA) or even that none of them were relevant under certain conditions and a particular task. To further investigate this situation, we performed the statistical correlations of VA and CS with all the functional vision parameters considering the data from both groups (SEQ and TOR) combined. We only obtained significant results ($p < 0.01$) between CS at 9 c/deg and some of the reading performance parameters (reading time, number of regressions, ratio of regressions).

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Correlation coefficients ranged from 0.27 to 0.33 (Spearman's rank coefficient) meaning that those subjects able to discriminate lower contrast thresholds scored better reading parameters. This was well in agreement with previous research on the psychophysics of reading [27]. Still, as mentioned previously, we did not obtain significant differences between groups fitted with different lenses as the inter-individual variability was too large.

The intrinsic differences in the optical design of toric and spherical lenses could have also influenced the visual differences between groups when performing these functional *dynamic* tasks. Spherical CLs have rotational symmetry about their axis, while toric lenses have different optical power at different meridians. For this reason, the optical quality provided by toric CLs could be affected by lens rotations, which was not the case with spherical CLs. In addition, the presence of higher order aberrations (HOA) induced by small displacements of the toric CL could also play a role.

We tested this hypothesis performing an optical simulation of the paragraph that subjects read, based on the convolution of the original non-aberrated text (the real size image as seen from the reading distance) with different aberrated Point Spread Functions (PSFs) corresponding to an average myopic subject (Sph = -2.3 D; Cyl = -1.0 D; Ax = 100°) after inducing a 10 deg rotation for a pupil diameter of 4.5 mm. We also included HOA up to the fifth order from a typical subject involved in the study, with an RMS of 0.16 µm and a predominance of vertical and horizontal coma and horizontal trefoil. The amount of rotation was chosen because the CL manufacturing parameters are limited and, in terms of cylinder axis, were available only in 10-degree steps. Therefore, the uncertainty on the prescription of the axis (defined as the highest accuracy available) was ±10 deg. These simulations do not include possible effects of neural adaptations [18]; they are monochromatic simulations of retinal images using Fourier optics [28].

Figure 6 shows some of the different simulations performed. Considering only the type of correction (spherical versus toric) the spherical lens displayed significantly more blur than the toric lens due to the uncorrected astigmatism inherent in this type of lens. However, the text with the spherical correction appeared to be still legible and it might be that at this particular letter size, the blur was not large enough to significantly alter reading performance, at least for the short time considered in this study. On the other hand, when rotations and HOA were added into the toric lens correction, the image quality decreased and showed blur levels similar to those of the spherical lens. Therefore, small errors in the measurement of the axis could partially explain why reading performance was similar in both groups.

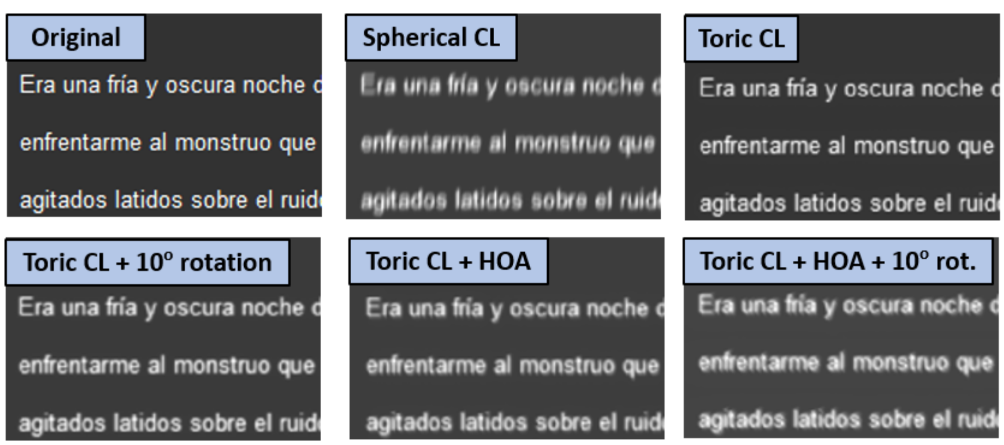

Fig. 6. Optical simulations of the retinal image obtained in different conditions related to this study.

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Finally, some limitations of the study should be noted. Although the groups were chosen demographically homogeneous, uniformity of visuomotor skills was not tested. This may have an impact on the performance of the functional tasks and contribute to the dispersion of the data. No chinrest was used in the e-mail and reading tests to fix the distance to the screen. The results may also be affected by possible adaptation effects, both for visual perceptual reasons and visuomotor adaptations. Lastly, no distinction was made between the different types of astigmatism.

5. Conclusions

In conclusion, it has been found that neophyte users of daily-disposable toric CLs showed a significant improvement in VA and CS tests compared to a similar sample of neophyte daily-disposable spherical CLs users. However, the functional tests specifically designed for this work did not render significant differences between toric and spherical CLs users.

We hypothesize that this situation was the result of a combination of several factors. While VA and CS tested vision to its performance limit, functional tests consisted of everyday situations in which maximum visual ability was not required. Along with this, image blur due to dynamic misalignments/rotations of the CL and the presence of HOA also tended to equalize the image quality displayed by both types of lenses.

Finally, it was important to note that the common clinical practice of correcting only the spherical equivalent in daily CLs in users with low to moderate astigmatism could not be justified in terms of optical and visual quality, especially if the CLs are intended to be used for precision tasks.

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Data availability. Data underlying the results presented in this paper are not publicly available at this time but may be obtained from the authors upon reasonable request.

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